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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,993	03/19/2004	Kurt Amplatz	20030372.ORI	8936
23595 7590 02/26/2007 NIKOLAI & MERSEREAU, P.A. 900 SECOND AVENUE SOUTH SUITE 820 MINNEAPOLIS, MN 55402			EXAMINER LANG, AMY T	
			ART UNIT	PAPER NUMBER
			3731	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/804,993

Applicant(s)

AMPLATZ ET AL.

Examiner

Amy T. Lang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 10, 11 and 14 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 12, 13 and 15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/3/2006, 6/10/2004.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

All previous rejections in office action filed 11/14/2006 have been withdrawn in view of applicant's arguments mailed 11/24/2006.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claims 3, 6, 9, and 12** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 6, 9, and 12 all disclose the diameter of the metal strands. However, it is the examiner's position that this claim limitation is indefinite since the applicant fails to disclose whether the diameter refers to the expanded or constrained configuration.

3. **Claim 13** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites wherein "the means for securing the braided metal strands at the proximal and distal end of the outer metal fabric is independent of the means for securing the braided metal strands at the proximal and distal ends of the inner metal fabric." However, claim 1, from which claim 13 is dependent, states that the securing means secures the "inner and outer metal fabrics together." Therefore, it is the

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examiner's position it is unclear how the securing means in claim 13 can be independent of the either the inner or outer metal fabric when the securing means is used to fasten the two together.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claim 1** is rejected under 35 U.S.C. 102(b) as being anticipated by Evans (US 2001/0031981 A1).

Evans discloses a device (19) with means for occluding an abnormal opening in a blood vessel (Figure 2, [0020]). Device 19 comprises inner and outer baskets (18 and 20 respectively) comprised of helical struts (30) ([0022], [0060], [0062]). As shown in Figures 3A and 2, baskets 18 and 20 comprise struts 30 in a braided configuration. Furthermore, the baskets are formed of a metal, specifically Nitinol, which clearly overlaps the instant claims ([0074]). Inner and outer baskets 18 and 20 are secured at proximal and distal ends with securing means (24 and 26) ([0062]). Additionally, the baskets expand in a radial orientation from a preset configuration ([0020], [0063]).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 2, 3, 6, 7, and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (US 2001/0031981 A1).

With regard to **claim 2**, Evans discloses the pitch of the struts of inner and outer baskets oriented with a local pitch ([0024]). Therefore, since Evans does not define the struts on each separate basket as comprising different pitches and that each comprises a local pitch, it would have been obvious to one of ordinary skill at the time of the invention for the pitches of the inner and outer baskets to be generally equal.

With regard to **claims 3 and 6**, Evans discloses the radial thickness (equivalent to diameter) of the struts from 0.001 to 0.050 inches ([0074]). Therefore, since each strut on the baskets can vary, it would have been obvious to one of ordinary skill at the time of the invention for the struts on the outer basket to be greater in diameter than the struts on the inner basket. Therefore, it would have been obvious for the outer basket to vary from 0.003 to 0.008 inches and the inner basket to vary from 0.001 to 0.002 inches, since both ranges fall within the values disclosed by Evans.

With regard to **claim 7**, Evans discloses an additional covering comprising a braided metallic material ([0069]; Figure 3Ba and 3C). Although Evans teaches that the coverings typically do not cover the over entire baskets 18 and 20, it would have been obvious to one of ordinary skill at the time of the invention for the coverings to be extend from the proximal to distal ends of both baskets 18 and 20 ([0069]). Therefore, the outer covering overlaps the instantly claimed outer metal fabric, outer basket 18 overlaps the instantly claimed inner metal fabric, and inner basket 20 overlaps the instantly claimed third metal fabric.

With regard to **claim 15**, Figures 5, 6, and 18B disclose alternative basket structures ([0070], [0088]). Therefore, it would have been obvious to one of ordinary skill at the time of the invention for either the inner or outer basket to comprise an alternative basket structure. The inner and outer basket would then comprise different geometrical shapes in an expanded configuration.

8. **Claims 1 and 3** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (US 2003/0074019 A1).

With regard to **claim 1**, Gray discloses a filter (52) comprising an outer braided fabric (54) and inner braided fabric (56) ([0037], Figures 4 and 5). The proximal and distal ends of the braided baskets are secured to the shaft (38) ([0038], [0039]). In another embodiment the filter braid comprises a metallic material ([0040]). Although Gray does not specifically disclose wherein the embodiment comprising fabric layers (54 and 56) is metallic, since Gray discloses in another embodiment a braided filter

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comprising a metallic material it would have been obvious to one of ordinary skill at the time of the invention for the first embodiment to also comprise metal.

Furthermore, Gray teaches that the filter is collapsible between a constrained and expanded configuration. The filter device of Gray is intrinsically capable of occluding an abnormal opening in a blood vessel.

With regard to **claim 3**, as shown in Figure 4, the outer braided fabric (56) intrinsically comprises a larger diameter than inner braided fabric (54) since it overlaps a larger surface area.

9. **Claims 4 and 5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (US 2003/0074019 A1) in view of Beck (US 2003/0199819 A1), and Mazzocchi (US 6,168,622 B1).

Gray discloses a filter device comprising two layers of braided metallic layers. However, Gray does not explicitly disclose the number of strands comprising each braided layer.

Beck teaches that filters are also utilized as occlusion devices (claim 4, page 3). Therefore, it would have been obvious to one of ordinary skill at the time of the invention for the filter of Gray to be used as an occlusion device.

Mazzocchi discloses an occlusion device comprising a metallic braided fabric (column 4, lines 30-45). The braided layer comprises about 72 strands, as is suitable for occluding an aneurysm (column 4, lines 57-64). Therefore, Mazzocchi clearly overlaps the instantly claimed 72 metal strands so that it would have been obvious for at

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least one layer of the device of Gray to also comprise 72 strands for use in occluding an aneurysm.

Additionally, Mazzocchi teaches that increasing the number of strands to 144 allows the device to function better and more efficiently as an occlusion device (column 14, line 57 through column 15, line 5). Therefore, it would have been obvious for at least one layer of the device of Gray to also comprise 144 strands for use in occluding an aneurysm. Since Gray is silent regarding the number of strands in each layer of fabric and Mazzocchi teaches the advantages of using layers of 72 and 144 strands, it would have been obvious to one of ordinary skill at the time of the invention for the device Gray to comprise an outer layer of 72 strands and an inner layer of 144 strands.

Allowable Subject Matter

10. **Claims 8, 10, 11, and 14** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter:

Evans, as show in Figure 4, discloses each basket comprising about 4 struts. Therefore, it would not have been obvious for the inner basket to comprise 144 struts and the outer basket to comprise 72 struts.

Gray discloses a filter comprising two layers of braided fabric but does not provide any motivation for having additional layers or braided fabric.

Burnside (US 2006/0266474 A1) discloses a three layer occlusion device comprised of a graft disposed on the inside and outside of a stent. Although both layers are braided, the graft does not comprise a metallic material.

Phelps (US 5,522,822) discloses a vasocclusion device comprised of two layers wherein the outer layer is a braided layer. However, the outer layer is not metallic and the inner layer is disclosed as a coil and not as braided.

Kotula (US 5,846,261) discloses a device to occlude an abnormal opening in a blood vessel. The device, as shown in Figure 24, comprises two layers of braided metallic fabric. However, the securing means (152) does not secure the proximal and distal ends of each fabric.

Mazzocchi (US 6,168,622 B1) discloses an aneurysm occlusion device comprised of a braided metallic fabric. The fabric utilizes 144 strands in the braid, but fails to disclose two or more layers of fabric.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy T. Lang whose telephone number is 571-272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

2/09/2007

AR


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
2/19/07